

Environmental Protection Agency

Pt. 156

§ 155.56 Interim registration review decision.

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in § 155.58 when issuing an interim registration review decision.

§ 155.57 Registration review decision.

A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA.

§ 155.58 Procedures for issuing a decision on a registration review case.

(a) The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place in the pesticide's registration review docket the Agency's proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things:

(1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.

(2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.

(3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or

final interim decision on a registration review case.

(4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

(c) After considering any comments on the proposed decision, the Agency will issue a registration review decision or interim registration review decision. This decision will include an explanation of any changes to the proposed decision and the Agency's response to significant comments. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a registration review decision or interim registration review decision. The registration review case docket will remain open until all actions required in the final decision on the registration review case have been completed.

(d) If the registrant fails to take the action required in a registration review decision or interim registration review decision, the Agency may take appropriate action under FIFRA.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

Subpart A—General Provisions

Sec.

156.3 Definitions.

156.10 Labeling requirements.

Subparts B–C [Reserved]

Subpart D—Human Hazard and Precautionary Statements

156.60 General.

156.62 Toxicity Category.

156.64 Signal word.

156.66 Child hazard warning.

156.68 First aid statement.

156.70 Precautionary statements for human hazards.

156.78 Precautionary statements for physical or chemical hazards.

Subpart E—Environmental Hazard and Precautionary Statements

156.80 General.

156.85 Non-target organisms.

Subparts F–G [Reserved]

Subpart H—Container Labeling

- 156.140 Identification of container types.
- 156.144 Residue removal instructions—general.
- 156.146 Residue removal instructions for nonrefillable containers—rigid containers with dilutable pesticides.
- 156.156 Residue removal instructions for refillable containers.
- 156.159 Compliance date.

Subparts I–J [Reserved]**Subpart K—Worker Protection Statements**

- 156.200 Scope and applicability.
- 156.203 Definitions.
- 156.204 Modification and waiver of requirements.
- 156.206 General statements.
- 156.208 Restricted-entry statements.
- 156.210 Notification-to-workers statements.
- 156.212 Personal protective equipment statements.

AUTHORITY: 7 U.S.C. 136–136y.

Subpart A—General Provisions**§ 156.3 Definitions.**

Terms used in this part have the same meaning as in the Act and part 152 of this chapter. In addition, as used in this part, the following terms shall have the meanings set forth below.

Dilutable means that the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use.

Transport vehicle means a cargo-carrying vehicle such as an automobile, van, tractor, truck, semitrailer, tank car or rail car used for the transportation of cargo by any mode.

[73 FR 64224, Oct. 29, 2008]

§ 156.10 Labeling requirements.

(a) *General*—(1) *Contents of the label*. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

- (i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;
- (ii) The name and address of the producer, registrant, or person for whom

produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility*. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used*. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General*. The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this section, and the misbranding provisions of the Act, “securely attached”

shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation*. While a pesticide product is in transit, the appropriate provisions of 49 CFR parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage*. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements*. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as “safe,” “nonpoisonous,” “noninjurious,” “harmless” or “nontoxic to humans and pets” with or without such a qualifying phrase as “when used as directed”; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) “Contains all natural ingredients”;

(B) “Among the least toxic chemicals known”

(C) “Pollution approved”

(6) *Final printed labeling*. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark*. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132.

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.*

(1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68 °F (20 °C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(7) For a pesticide product packaged in a refillable container, an appropriately sized area on the label may be left blank to allow the net weight or measure of content to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribu-

tion or sale of the pesticide. As required in paragraph (a)(1)(iii) of this section, the net contents must be shown clearly and prominently on the label.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishment's registration number.* The producing establishment registration number preceded by the phrase "EPA Est.," of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. For a pesticide product packaged in a refillable container, an appropriately sized area on the label may be left blank after the phrase "EPA Est." to allow the EPA establishment registration number to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribution or sale of the pesticide.

(g) *Ingredient statement—(1) General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The

statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing

batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) [Reserved]

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use.* (A) Detailed directions for use may be omitted from labeling of

pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repackaging for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Worker protection statements meeting the requirements of subpart K of this part.

(ix) Specific directions concerning the storage, residue removal and disposal of the pesticide and its container, in accordance with subpart H of this part. These instructions must be grouped and appear under the heading, "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See table in § 156.60(b))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) For total release foggers as defined in § 156.78(d)(1), the following

statements must be included in the "Directions for Use."

DO NOT use more than one fogger per room. DO NOT use in small, enclosed spaces such as closets, cabinets, or under counters or tables. Do not use in a room 5 ft.x5 ft. or smaller; instead, allow fog to enter from other rooms. Turn off ALL ignition sources such as pilot lights (shut off gas valves), other open flames, or running electrical appliances that cycle off and on (i.e., refrigerators, thermostats, etc.). Call your gas utility or management company if you need assistance with your pilot lights."

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of use classification.* Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978. Redesignated and amended at 53 FR 15991, 15999, May 4, 1988; 57 FR 38146, Aug. 21, 1992; 60 FR 32096, June 19, 1995; 63 FR 9082, Feb. 23, 1998; 66 FR 64764, Dec. 14, 2001; 71 FR 47420, Aug. 16, 2006; 73 FR 75596, Dec. 12, 2008]

Subparts B-C [Reserved]

Subpart D—Human Hazard and Precautionary Statements

SOURCE: 66 FR 64764, Dec. 14, 2001, unless otherwise noted.

§ 156.60 General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either

§ 156.62

direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) *Location of statements*—(1) *Front panel statements.* The signal word, child hazard warning, and, in certain cases, the first aid statement are required to appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) *Statements elsewhere on label.* Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) *Placement and prominence*—(1) *Front panel statements.* All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

40 CFR Ch. I (7–1–10 Edition)

TYPE SIZES FOR FRONT PANEL WARNING STATEMENTS

Size of Label Front Panel (Square Inches)	Point Size	
	Signal Word (All Capital Letters)	Child Hazard Warning
5 and under	6	6
Over 5 to 10	10	6
Over 10 to 15	12	8
Over 15 to 30	14	10
Over 30	18	12

(2) *Other required statements.* All other hazard and precautionary statements must be at least 6 point type.

§ 156.62 Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In addition, toxicity categories may be used for regulatory purposes other than labeling, such as classification for restricted use and requirements for child-resistant packaging. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table in this paragraph.

ACUTE TOXICITY CATEGORIES FOR PESTICIDE PRODUCTS

Hazard Indicators	I	II	III	IV
Oral LD ₅₀	Up to and including 50 mg/kg	>50 thru 500 mg/kg	>500 thru 5,000 mg/kg	>5,000 mg/kg
Dermal LD ₅₀	Up to and including 200 mg/kg	>200 thru 2000 mg/kg	>2000 thru 20,000 mg/kg	>20,000 mg/kg
Inhalation LC ₅₀	Up to and including 0.2 mg/liter	>0.2 thru 2 mg/liter	>2 thru 20 mg/liter	>20 mg/liter
Eye irritation	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin irritation	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

§ 156.64 Signal word.

(a) *Requirement.* Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal

word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in §156.62. The signal word

must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) *Toxicity Category I.* Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word "DANGER." In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word "Poison" must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word "Poison."

(2) *Toxicity Category II.* Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word "WARNING."

(3) *Toxicity Category III.* Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word "CAUTION."

(4) *Toxicity Category IV.* A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be "CAUTION."

(b) *Use of signal words.* In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

§ 156.66 Child hazard warning.

(a) Each pesticide product must bear on the front panel of the label the statement "Keep Out of Reach of Chil-

dren." That statement, or any alternative statement approved by EPA, must appear on a separate line in close proximity to the signal word, if required. The statement is required on Toxicity Category IV products that do not otherwise require a signal word.

(b) In its discretion, EPA may waive the requirement, or require or permit an alternative child hazard warning, if:

(1) The applicant can demonstrate that the likelihood of exposure of children to the pesticide during distribution, marketing, storage or use is remote (for example, an industrial use product); or

(2) The pesticide is approved for use on children (for example, an insect repellent).

(c) EPA may approve an alternative child hazard warning that more appropriately reflects the nature of the pesticide product to which children may be exposed (for example, an impregnated pet collar). In this case, EPA may also approve placement on other than the front panel.

§ 156.68 First aid statement.

(a) *Product as sold and distributed.* Each product must bear a first aid statement if the product has systemic effects in Category I, II, or III, or skin or eye irritation effects in Category I or II.

(b) *Product as diluted for use.* If the product labeling bears directions for dilution with water prior to use, the label may also include a statement describing how the first aid measures may be modified for the diluted product. Such a statement must reflect the Toxicity Category(ies) of the diluted product, based upon data for the route of exposure (or calculations if appropriate). If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. The statement for a diluted product may not substitute for the statement for the concentrate, but augments the information provided for the concentrate.

(c) *Heading.* The heading of the statement may be "First Aid" or "Statement of Practical Treatment."

(d) *Location of first aid statement.* The first aid statement must appear on the front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statement if a reference such as “See first aid statement on back panel” appears on the front panel. The first aid statement for products assigned to Toxicity Categories II or III may appear on any panel of the label.

§ 156.70 Precautionary statements for human hazards.

(a) *Requirement.* Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading “Precautionary Statements” and under appropriate subheadings similar to “Humans and Domestic Animals,” “Environmental Hazards” (see subpart E of this part) and “Physical or Chemical Hazards.” The phrase “and Domestic Animals” may be omitted from the

heading if domestic animals will not be exposed to the product.

(b) *Content of statements.* When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) *Typical precautionary statements.* The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to §156.68(b) for requirements for use dilution statements.

TYPICAL HUMAN HAZARD AND PRECAUTIONARY STATEMENTS

Toxicity Category	Systemic effects (oral, dermal, inhalation toxicity)	Irritation effects (skin and eye)	Sensitizer (There are no categories of sensitization.)
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel first aid statement required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Front panel first aid statement required.]	If product is a sensitizer: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
II	May be fatal if swallowed, [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statement required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]	
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing.	
IV	No precautionary statements required	No precautionary statements required.	

§ 156.78 Precautionary statements for physical or chemical hazards.

(a) *Requirement.* Warning statements on the flammability or explosive char-

acteristics of the pesticide product are required if a product meets the criteria in this section. Warning statements pertaining to other physical/chemical

hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis.

(b) *Pressurized products.* The table below sets out the required flammability label statements for pressurized products.

FLAMMABILITY STATEMENTS FOR PRESSURIZED PRODUCTS

Flash point/flame extension of product	Required labeling statement
---Flash point at or below 20 °F OR ---Flashback at any valve opening	<i>Extremely flammable.</i> Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
---Flash point >20 °F to 80 °F OR ---Flame extension more than 18 in. long at a distance of 6 in from the flame	<i>Flammable.</i> Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
All other pressurized products	<i>Contents under pressure.</i> Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.

(c) *Non-pressurized products.* The table below sets out the required flammability label statements for non-pressurized products.

FLAMMABILITY STATEMENTS FOR NON-PRESSURIZED PRODUCTS

Flash point	Required labeling statement
At or below 20 °F	<i>Extremely flammable.</i> Keep away from fire, sparks and heated surfaces.
Greater than 20 °F to 80 °F	<i>Flammable.</i> Keep away from heat and open flame.
Greater than 80 °F to 150 °F	<i>Combustible.</i> Do not use or store near heat or open flame.

(d) *Total release fogger products.* (1) A *total release fogger* is defined as a pesticide product in a pressurized container designed to automatically re-

lease the total contents in one operation, for the purpose of creating a permeating fog within a confined space to deliver the pesticide throughout the space.

(2) If a pesticide product is a total release fogger containing a propellant with a flash point at or below 20 °F, then the following special instructions must be added to the "Physical and Chemical Hazards" warning statement, in addition to any flammability statement required by paragraph (b) of this section:

This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the Directions for Use on this label very carefully.

(3) A graphic symbol depicting fire, such as illustrated in this paragraph, or an equivalent symbol, must be displayed along with the required language adjoining the "Physical and Chemical Hazards" warning statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word.



Highly Flammable Ingredient
 Ingrediente Altamente Inflamable

Subpart E—Environmental Hazard and Precautionary Statements

SOURCE: 66 FR 64767, Dec. 14, 2001, unless otherwise noted.

§ 156.80 General.

(a) *Requirement.* Each product is required to bear hazard and precautionary statements for environmental hazards, including hazards to non-target organisms, as prescribed in this subpart. Hazard statements describe the type of hazard that may be present, while precautionary statements direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(b) *Location of statements.* Environmental hazard and precautionary

statements may appear on any panel of the label and may be required also in supplemental labeling. The environmental hazard statements must appear together under the heading "Environmental Hazards." Typically the statements are grouped as a sub-category within the "Precautionary Statements" section of the labeling.

(c) *Type size.* All environmental hazard and precautionary statements must be at least 6 point type.

§ 156.85 Non-target organisms.

(a) *Requirement.* Where a hazard exists to non-target organisms, EPA may require precautionary statements of the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage.

(b) *Examples.* The statements in this paragraph illustrate the types of hazard statements that EPA may require and the circumstances under which they are typically required. These statements are not comprehensive; other statements may be required if more appropriate to the formulation or use.

(1) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD₅₀ of 100 mg/kg or less, the statement, "This pesticide is toxic to wildlife" is required.

(2) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC₅₀ of 1 ppm or less, the statement, "This pesticide is toxic to fish" is required.

(3) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD₅₀ of 100 mg/kg or less, or a subacute dietary LC₅₀ of 500 ppm or less, the statement, "This pesticide is toxic to wildlife" is required.

(4) If either accident history or field studies demonstrate that the use of the pesticide may result in fatality to birds, fish or mammals, the statement, "This pesticide is extremely toxic to wildlife (fish)" is required.

(5) If a product is intended for or involves foliar application to agricultural crops, forests or shade trees, or mosquito abatement treatments, and contains a pesticide toxic to polli-

nating insects, the label must bear appropriate label cautions.

(6) If a product is intended for outdoor use other than aquatic applications, the label must bear the caution, "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

Subparts F-G [Reserved]

Subpart H—Container Labeling

SOURCE: 71 FR 47420, Aug. 16, 2006, unless otherwise noted.

§ 156.140 Identification of container types.

For products other than plant-incorporated protectants, the following statements, as applicable, must be placed on the label or container. The information may be located on any part of the container except the closure. If the statements are placed on the container, they must be durably marked on the container. Durable marking includes, but is not limited to etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, or marking with durable ink.

(a) *Nonrefillable container.* For non-refillable containers, the statements in paragraphs (a)(1) through (a)(4) of this section are required except as provided in paragraphs (a)(5), (c), (d), and (e) of this section. If placed on the label, the statements in paragraphs (a)(1) through (a)(3) of this section must be under an appropriate heading under the heading "Storage and Disposal." If any of the statements in paragraphs (a)(1) through (a)(3) of this section are placed on the container, an appropriate referral statement such as "See container for recycling [or other descriptive word] information." must be placed on the label under the heading "Storage and Disposal."

(1) *Statement identifying a nonrefillable container.* The following phrase is required: "Nonrefillable container."

(2) *Reuse statement.* One of the following statements is required. Products with labels that allow household/residential use must use the statement in paragraph (a)(2)(i) or (a)(2)(iii) of this section. All other products must

use the statement in paragraph (a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section.

(i) "Do not reuse or refill this container."

(ii) "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."

(iii) The following statement may be used if a product is "ready-to-use" and its directions for use allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container."

(3) *Recycling or reconditioning statement.* One of the following statements is required:

(i) "Offer for recycling if available."

(ii) "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [a pesticide container recycling organization] at [phone number] or [web site]. For example, this statement could be "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council (ACRC) at 1-877-952-2272 (toll-free) or www.acrecycle.org."

(iii) A recycling statement approved by EPA and published in an EPA document, such as a Pesticide Registration Notice.

(iv) An alternative recycling statement that has been reviewed and approved by EPA.

(v) "Offer for reconditioning if appropriate."

(4) *Batch code.* A lot number, or other code used by the registrant or producer to identify the batch of the pesticide product which is distributed and sold is required.

(5) *Exemptions.* Pesticide products in the following types of nonrefillable containers, and their packaging, are exempt from the requirements in paragraphs (a)(1) and (a)(2) of this section:

(i) Aerosol cans.

(ii) Devices as defined in § 152.500 of this chapter.

(iii) One-time use caulking tubes and other one-time use squeezable tube containers for paste, gel, or other similar substances.

(iv) Foil packets for water soluble packaging, repellent wipes, and other one-time use products.

(v) One-time use portion control packets, such as polyethylene sleeve packages, or rodenticide placepacks.

(vi) One-time use bait stations.

(vii) One-time use cages for repellent or trapping strips.

(viii) Pet collars or animal ear tags, such as cattle ear tags.

(ix) One-time use semiochemical dispersion devices.

(x) Any container that is destroyed by the use of the product contained.

(xi) Any container that would be destroyed if reuse of the container were attempted.

(b) *Refillable container.* For refillable containers, one of the following statements is required, except as provided in paragraphs (c), (d), and (e) of this section. If placed on the label, the statement must be under the heading "Storage and Disposal." If the statement is placed on the container, an appropriate referral statement, such as "Refilling limitations are on the container," must be placed under the heading "Storage and Disposal."

(1) "Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose."

(2) "Refillable Container. Refill this container with [common chemical name] only. Do not reuse this container for any other purpose."

(c) *Modification.* EPA may, on its own initiative or based on data or information submitted by any person, modify or waive the requirements of this section or permit or require alternative labeling statements.

(d) *Exemption for articles.* Pesticidal articles that are not exempted from FIFRA regulation by § 152.25(a) of this

§ 156.144

chapter are exempt from the requirements of this section.

(e) *Exemption for transport vehicles.* Transport vehicles are exempt from the requirements of this section.

[71 FR 47420, Aug. 16, 2006, as amended at 73 FR 64224, Oct. 29, 2008]

§ 156.144 Residue removal instructions—general.

(a) *General.* Except as provided by paragraphs (c) through (g) of this section, the label of each pesticide product must include the applicable instructions for removing pesticide residues from the container prior to container disposal that are specified in § 156.146 and § 156.156. The residue removal instructions are required for both nonrefillable and refillable containers.

(b) *Placement of residue removal statements.* All residue removal instructions must be placed under the heading “Storage and Disposal.”

(c) *Exemption for residential/household use products.* Residential/household use pesticide products are exempt from the residue removal instruction requirements in this section through § 156.156.

(d) *Modification.* EPA may, on its own initiative or based on data submitted by any person, modify or waive the requirements of this section through § 156.156, or permit or require alternative labeling statements.

(e) *Exemption for gases.* Pesticide products that are gaseous at atmospheric temperature and pressure are exempt from the residue removal instruction requirements in this section through § 156.156.

(f) *Exemption for articles.* Pesticidal articles that are not exempted from FIFRA regulation by § 152.25(a) of this chapter are exempt from the residue removal instruction requirements in this section through § 156.156.

(g) *Exemption for transport vehicles.* Transport vehicles are exempt from the requirements in this section through § 156.156.

[71 FR 47420, Aug. 16, 2006, as amended at 73 FR 64224, Oct. 29, 2008]

40 CFR Ch. I (7–1–10 Edition)

§ 156.146 Residue removal instructions for nonrefillable containers—rigid containers with dilutable pesticides.

The label of each dilutable (liquid or solid) pesticide product packaged in a rigid nonrefillable container must include the following residue removal instructions as appropriate.

(a) *Timing of the residue removal procedure.* One of the following statements must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraphs (b) and (c) of this section:

(1) “Clean container promptly after emptying.”

(2) “Triple rinse or pressure rinse container (or equivalent) promptly after emptying.”

(3) “Triple rinse container (or equivalent) promptly after emptying.”

(b) *Triple rinse instructions.* The label of each dilutable pesticide product packaged in rigid nonrefillable containers must include one of the following sets of instructions.

(1) For liquid dilutable pesticide products in containers small enough to shake, use the following instructions: “Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.”

(2) For solid dilutable pesticide products in containers small enough to shake, use the following instructions: “Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.”

(3) For containers that are too large to shake, use the following instructions: “Triple rinse as follows: Empty remaining contents into application

equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."

(c) *Pressure rinse instructions.* The label of each dilutable pesticide product packaged in rigid nonrefillable containers may include one of the following sets of instructions, and one of them must be used if the statement in paragraph (a)(2) of this section is used. If one of these statements is included on the label, it must immediately follow the triple rinse instructions specified in paragraph (b) of this section.

(1) For liquid dilutable pesticide products, use the following label instruction: "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

(2) For solid dilutable pesticide products, use the following label instruction: "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

(d) *Non-water diluent.* (1) A registrant who wishes to require users to clean a container with a diluent other than water (e.g., solvents) must submit to EPA a written request to modify the residue removal instructions of this section. The registrant may not distribute or sell the pesticide with the

modified residue removal instructions until EPA approves the request in writing.

(2) The registrant must indicate why a non-water diluent is necessary for efficient residue removal, and must propose residue removal instructions and disposal instructions that are appropriate for the characteristics and formulation of the pesticide product and non-water diluent. The proposed residue removal instructions must identify the diluent. If the Directions for Use permit the application of a mixture of the pesticide and the non-water diluent, the instructions may allow the rinsate to be added to the application equipment or mix tank. If the Directions for Use do not identify the non-water diluent as an allowable addition to the pesticide, the instructions must require collection and storage of the rinsate in a rinsate collection system.

(3) EPA may approve the request if EPA finds that the proposed instructions are necessary and appropriate.

§ 156.156 Residue removal instructions for refillable containers.

The label of each pesticide product packaged in a refillable container must include the residue removal instructions in this section. Instructions must be given for all pesticide products that are distributed or sold in refillable containers, including those that do not require dilution prior to application.

(a) *Timing of the residue removal procedure.* One of the following statements must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraph (b) of this section:

(1) "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."

(2) "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."

(b) *Residue removal instructions prior to container disposal.* (1) Instructions for cleaning each refillable container prior to disposal are required. The residue

removal instructions must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.

(2) Subject to meeting the standard in paragraph (b)(1) of this section, the statement on residue removal instructions could include any one of the following:

(i) The refilling residue removal procedure developed by the registrant for the pesticide product.

(ii) Standard industry practices for cleaning refillable containers.

(iii) For pesticides that require dilution prior to application, the following statement: "To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."

(iv) Any other statement the registrant considers appropriate.

§ 156.159 Compliance date.

Any pesticide product released for shipment by a registrant after August 16, 2010 must bear a label that complies with §§ 156.10(d)(7), 156.10(f), 156.10(i)(2)(ix), 156.140, 156.144, 156.146, and 156.156.

[73 FR 64224, Oct. 29, 2008]

EFFECTIVE DATE NOTE: At 75 FR 33708, June 15, 2010, § 156.159 was revised, effective Aug. 16, 2010. For the convenience of the user, the revised text is set forth as follows:

§ 156.159 Compliance date.

Any pesticide product released for shipment by a registrant after December 16, 2010 must bear a label that complies with §§ 156.10(d)(7), 156.10(f), 156.10(i)(2)(ix), 156.140, 156.144, 156.146 and 156.156.

Subparts I-J [Reserved]

Subpart K—Worker Protection Statements

SOURCE: 57 FR 38146, Aug. 21, 1992, unless otherwise noted.

§ 156.200 Scope and applicability.

(a) *Scope.* (1) This subpart prescribes statements that must be placed on the pesticide label and in pesticide labeling. These statements incorporate by reference the Worker Protection Standard, part 170 of this chapter. The requirements addressed in these statements are designed to reduce the risk of illness or injury resulting from workers' and pesticide handlers' occupational exposures to pesticides used in the production of agricultural plants on agricultural establishments as defined in § 170.3 of this chapter. These statements refer to specific workplace practices designed to reduce or eliminate exposure and to respond to emergencies that may arise from the exposures that may occur.

(2) This subpart prescribes interim requirements that must be placed on the pesticide label and in pesticide labeling. These interim requirements pertain to restricted-entry intervals, personal protective equipment, and notification. On a case-by-case basis, these interim requirements will be reviewed and may be revised during re-registration or other agency review processes.

(b) *Applicability.* (1) The requirements of this subpart apply to each pesticide product that bears directions for use in the production of any agricultural plant on any agricultural establishment as defined in § 170.3 of this chapter, or whose labeling reasonably permits such use.

(2) The requirements of this subpart do not apply to a product that bears directions solely for uses excepted by § 170.202(b) of this chapter.

(c) *Effective dates.* No product to which this subpart applies shall be distributed or sold without amended labeling by any registrant after April 21, 1994, or by any person after October 23, 1995.

[57 FR 38146, Aug. 21, 1992, as amended at 73 FR 75596, Dec. 12, 2008]

§ 156.203 Definitions.

Terms in this subpart have the same meanings as they do in the Federal Insecticide, Fungicide, and Rodenticide

Act, as amended. In addition, the following terms, as used in this subpart, shall have the meanings stated below:

Fumigant means any pesticide product that is a vapor or gas or forms a vapor or gas on application and whose method of pesticidal action is through the gaseous state.

Restricted-entry interval or REI means the time after the end of a pesticide application during which entry to the treated area is restricted.

[57 FR 38146, Aug. 21, 1992, as amended at 73 FR 75596, Dec. 12, 2008]

§ 156.204 Modification and waiver of requirements.

(a) *Modification on Special Review.* If the Agency concludes in accordance with § 154.25(c) of this chapter that a pesticide should be placed in Special Review because the pesticide meets or exceeds the criteria for human health effects of § 154.7(a)(1)(2) or (6) of this chapter, the Agency may modify the personal protective equipment required for handlers or early-entry workers or both, the restricted-entry intervals, or the notification to workers requirements.

(b) *Other modifications.* The Agency, pursuant to this subpart and authorities granted in FIFRA sections 3, 6, and 12, may, on its initiative or based on data submitted by any person, modify or waive the requirements of this subpart, or permit or require alternative labeling statements. Supporting data may be either data conducted according to Subdivisions U or K of the Pesticide Assessments guidelines or data from medical, epidemiological, or health effects studies. A registrant who wishes to modify any of the statements required in §§ 156.206, 156.208, 156.210, or 156.212 must submit an application for amended registration unless specifically directed otherwise by the Agency.

[57 FR 38146, Aug. 21, 1992, as amended at 73 FR 75596, Dec. 12, 2008]

§ 156.206 General statements.

(a) *Application restrictions.* Each product shall bear the statement: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area

during application." This statement shall be near the beginning of the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(b) *40 CFR part 170 reference statement.*

(1) Each product shall bear the reference statement: "Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170." This statement shall be placed on the product label under the heading AGRICULTURAL USE REQUIREMENTS.

(2) Each product shall bear the statement: "This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label [in this labeling] about [use any of the following that are applicable] personal protective equipment, restricted-entry interval, and notification to workers." These statements shall be placed immediately following the reference statement required by paragraph (b)(1) of this section, or they shall be placed in the supplemental product labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(3) If the statements in paragraph (b)(2) of this section are included in supplemental labeling rather than on the label of the pesticide container, the container label must contain this statement immediately following the statement required in paragraph (b)(1) of this section: "Refer to supplemental labeling entitled AGRICULTURAL USE REQUIREMENTS in the DIRECTIONS FOR USE section of the labeling for information about this standard."

(4) If the statements in paragraph (b)(2) of this section are included in supplemental labeling, they must be preceded immediately by the statement in paragraph (b)(1) of this section under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(c) *Product-type identification.* (1) If the product contains an organophosphate (i.e., an

organophosphorus ester that inhibits cholinesterase) or an *N*-methyl carbamate (*i.e.*, an *N*-methyl carbamic acid ester that inhibits cholinesterase), the label shall so state. The statement shall be associated with the product name or product-type identification or shall be in the STATEMENT OF PRACTICAL TREATMENT or FIRST AID section of the label.

(2) If the product is a fumigant, the label shall so state. The identification shall appear:

- (i) As part of the product name; or
- (ii) Close to the product name, as part of the product-type identification or as a separate phrase or sentence.

(d) *State restrictions.* Each product shall bear the statement: "For any requirements specific to your State, consult the agency in your State responsible for pesticide regulation." This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(e) *Spanish warning statements.* If the product is classified as toxicity category I or toxicity category II according to the criteria in §156.62, the signal word shall appear in Spanish in addition to English followed by the statement, "Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)" The Spanish signal word "PELIGRO" shall be used for products in toxicity category I, and the Spanish signal word "AVISO" shall be used for products in toxicity category II. These statements shall appear on the label close to the English signal word.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993; 73 FR 75596, Dec. 12, 2008]

§ 156.208 Restricted-entry statements.

(a) *Requirement.* Each product with a restricted-entry interval shall bear the following statement: "Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI)." This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(b) *Location of specific restricted-entry interval statements.* (1) If a product has one specific restricted-entry interval

applicable to all registered uses of the product on agricultural plants, the restricted-entry interval for the product shall appear as a continuation of the statement required in paragraph (a) of this section and shall appear as follows: "of X hours" or "of X days" or "until the acceptable exposure level of X ppm or mg/m³ is reached."

(2) If different restricted-entry intervals have been established for some crops or some uses of a product, the restricted-entry statement in paragraph (b)(1) of this section shall be associated on the labeling of the product with the directions for use for each crop each use to which it applies, immediately preceded or immediately followed by the words "Restricted-entry interval" (or the letters "REI").

(c) *Restricted-entry interval based on toxicity of active ingredient*—(1) *Determination of toxicity category.* A restricted-entry interval shall be established based on the acute toxicity of the active ingredients in the product. For the purpose of setting the restricted-entry interval, the toxicity category of each active ingredient in the product shall be determined by comparing the obtainable data on the acute dermal toxicity, eye irritation effects, and skin irritation effects of the ingredient to the criteria of §156.62. The most toxic of the applicable toxicity categories that are obtainable for each active ingredient shall be used to determine the restricted-entry interval for that product. If no acute dermal toxicity data are obtainable, data on acute oral toxicity also shall be considered in this comparison. If no applicable acute toxicity data are obtainable on the active ingredient, the toxicity category corresponding to the signal word of any registered manufacturing-use product that is the source of the active ingredient in the end-use product shall be used. If no acute toxicity data are obtainable on the active ingredients and no toxicity category of a registered manufacturing-use product is obtainable, the toxicity category of the end-use product (corresponding to the signal word on its labeling) shall be used.

(2) *Restricted-entry interval for sole active ingredient products.* (i) If the product contains only one active ingredient

and it is in toxicity category I by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 48 hours. If, in addition, the active ingredient is an organophosphorus ester that inhibits cholinesterase and that may be applied outdoors in an area where the average annual rainfall for the application site is less than 25 inches per year, the following statement shall be added to the restricted-entry interval statement: "(72 hours in outdoor areas where average annual rainfall is less than 25 inches a year)."

(ii) If the product contains only one active ingredient and it is in toxicity category II by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 24 hours.

(iii) If the product contains only active ingredients that are in toxicity category III or IV by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 12 hours.

(3) *Restricted-entry interval for multiple active ingredient products.* If the product contains more than one active ingredient, the restricted-entry interval (including any associated statement concerning use in arid areas under paragraph (c)(2)(i) of this section) shall be based on the active ingredient that requires the longest restricted-entry interval as determined by the criteria in this section.

(d) *Exception for fumigants.* The criteria for determining restricted-entry intervals in paragraph (c) of this section shall not apply to any product that is a fumigant. For fumigants, any existing restricted-entry interval (hours, days, or acceptable exposure level) shall be retained. Entry restrictions for fumigants have been or shall be established on a case-by-case basis at the time of registration, reregistration, or other Agency review process.

(e) *Existing product-specific restricted-entry intervals.* (1) A product-specific restricted-entry interval, based on data collected in accordance with § 158.1070 or § 161.390 of this chapter and Subdivision K of the Pesticide Assessment Guidelines, shall supersede any restricted-entry interval applicable to the product under paragraph (c) of this section.

(2) Product-specific restricted-entry intervals established for pesticide products or pesticide uses that are not covered by part 170 of this chapter shall remain in effect and shall not be placed under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(f) *Existing interim restricted-entry intervals.* (1) An interim restricted-entry interval established by the Agency before the effective date of this subpart will continue to apply unless a longer restricted-entry interval is required by paragraph (c) of this section.

(2) Existing interim restricted-entry intervals established by the Agency for pesticide products or pesticide uses not covered by part 170 of this chapter shall remain in effect and shall not be placed under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993; 72 FR 61028, Oct. 26, 2007; 73 FR 75596, Dec. 12, 2008]

§ 156.210 Notification-to-workers statements.

(a) *Requirement.* Each product that meets the requirements of paragraph (b) of this section shall bear the posting and oral notification statements prescribed below. The statements shall be in the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(b) *Notification to workers of pesticide application.* (1) Each product that contains any active ingredient classified as toxicity category I for either acute dermal toxicity or skin irritation potential under the criteria in § 156.62 shall bear the statement: "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas." If no acute dermal toxicity data are obtainable, data on acute oral toxicity of the active ingredient shall be considered instead. If no data on acute dermal toxicity, skin irritation potential, or acute oral toxicity are obtainable on the active ingredient, the toxicity category corresponding to the signal word of any registered manufacturing-use product that is the source of the active ingredient in the end-use product shall be used. If none of the applicable acute

toxicity data are obtainable on the active ingredient and no toxicity category of the registered manufacturing-use product is obtainable, the toxicity category of the end-use product corresponding to the product's signal word shall be used.

(2) Each product that is a fumigant and is registered for use in a greenhouse (or whose labeling allows use in a greenhouse) shall bear the statement: "For greenhouse applications, notify workers of the application by warning them orally and by posting warning signs outside all entrances to the greenhouse."

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993; 73 FR 75596, Dec. 12, 2008]

§ 156.212 Personal protective equipment statements.

(a) *Requirement.* Each product shall bear the personal protective equipment statements prescribed in paragraphs (d) through (j) of this section.

(b) *Exceptions.* (1) If personal protective equipment were required for a product before the effective date of this subpart, the existing requirements shall be retained on the labeling wherever they are more specific or more protective (as specified in EPA guidance materials) than the requirements in the table in paragraph (e) of this section.

(2) Any existing labeling statement that prohibits the use of gloves or boots overrides the corresponding requirement in paragraph (e) of this section and must be retained on the labeling.

(3) If the product labeling contains uses that are not covered by part 170 of this chapter, the registrant may adopt the personal protective equipment required in this section for those uses. However, if the personal protective equipment required in this section would not be sufficiently protective or would be onerously overprotective for uses not covered by part 170 of this chapter, the registrant must continue to apply the existing personal protective equipment requirements to those uses. The labeling must indicate which personal protective equipment requirements apply to uses covered by part 170 of this chapter and which personal pro-

TECTIVE equipment requirements apply to other uses.

(c) *Location of personal protective equipment statements.*—(1) *Personal protective equipment statements for pesticide handlers.* Personal protective equipment statements for pesticide handlers shall be in the HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) section of the labeling. The required statements may be combined to avoid redundancy as long as the requirements and conditions under which they apply are identified.

(2) *Personal protective equipment statements for early-entry workers.* Personal protective equipment statements for early-entry workers shall be placed in the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS and immediately after the restricted-entry statement required in § 156.208(a).

(d) *Personal protective equipment statements for pesticide handlers.* (1) The table in paragraph (e) of this section specifies minimum requirements for personal protective equipment (as defined in § 170.240 of this chapter) and work clothing for pesticide handlers. This personal protective equipment requirement applies to any product that presents a hazard through any route of exposure identified in the table (acute dermal toxicity, skin irritation potential, acute inhalation toxicity, and eye irritation potential).

(2) The requirement for personal protective equipment is based on the acute toxicity category of the end-use product for each route of exposure as defined by § 156.62. If data to determine the acute dermal toxicity or the acute inhalation toxicity are not obtainable, the acute oral toxicity shall be used as a surrogate to determine the personal protective equipment requirements for that route of exposure. If data to determine the acute toxicity of the product by a specific route of exposure (including acute oral toxicity in lieu of acute dermal or acute inhalation toxicity) are not obtainable, the toxicity category corresponding to the signal word of the end-use product shall be used to

determine personal protective equipment requirements for that route of exposure. If the signal word is "CAUTION," toxicity category III will be used.

(3) The minimum personal protective equipment and work clothing requirements specified in this section shall be included in a statement such as the following: "Applicators and other handlers must wear: (body protection statement); (glove statement, if appli-

cable); (footwear statement, if applicable); (protective eyewear statement, if applicable); (respirator statement, if applicable)." The format of statements given in this paragraph is optional, but it is recommended for clarity.

(e) *Summary of personal protective equipment requirements.* The following table 1 summarizes the personal protective equipment requirements by route of exposure and toxicity category:

TABLE 1—MINIMUM PERSONAL PROTECTIVE EQUIPMENT (PPE) AND WORK CLOTHING FOR HANDLING ACTIVITIES

Route of Exposure	Toxicity Category of End-Use Product			
	I	II	III	IV
Dermal Toxicity or Skin Irritation Potential ¹	Coveralls worn over long-sleeved shirt and long pants Socks Chemical-resistant footwear Chemical-resistant gloves ²	Coveralls worn over short-sleeved shirt and short pants Socks Chemical-resistant footwear Chemical-resistant gloves ²	Long-sleeved shirt and long pants Socks Shoes Chemical-resistant gloves ²	Long-sleeved shirt and long pants Socks Shoes No minimum ⁴
Inhalation Toxicity	Respiratory protection device ³	Respiratory protection device ³	No minimum ⁴	No minimum ⁴
Eye Irritation Potential	Protective eyewear	Protective eyewear	No minimum ⁴	No minimum ⁴

¹ If dermal toxicity and skin irritation potential are in different toxicity categories, protection shall be based on the more toxic (lower numbered) category.

² For labeling language for chemical-resistant gloves, see paragraph (f) of this section.

³ For labeling language for respiratory protection device, see paragraphs (g) and (h) of this section.

⁴ Although no minimum PPE is required by this section for this toxicity category and route of exposure, the Agency may require PPE on a product-specific basis.

(f) *Chemical-resistant gloves labeling statements for pesticide handlers.* If the table in paragraph (e) of this section indicates that chemical-resistant gloves are required, the glove statement shall be as specified in paragraph (f)(2), (3), (4), or (5) of this section.

(1) *Exception.* The registrant shall specify a glove type other than that selected through the criteria in paragraphs (f)(2) through (5) of this section if information available to the registrant indicates that such a glove type is more appropriate or more protective than the glove type specified in this section. The statement must specify the particular types of chemical-resistant glove (such as nitrile, butyl, neoprene, and/or barrier-laminate).

(2) *Solid formulations.* For products formulated and applied as solids or formulated as solids and diluted solely with water for application, the glove

statement shall specify: "waterproof gloves."

(3) *Aqueous-based formulations.* For products formulated and applied as a water-based liquid or formulated as a water-based liquid and diluted solely with water for application, the glove statement may specify: "waterproof gloves" instead of the statement in paragraph (f)(4) of this section.

(4) *Other liquid formulations.* For products formulated or diluted with liquids other than water, the glove statement shall specify: "chemical-resistant (such as nitrile or butyl) gloves."

(5) *Gaseous formulations and applications.* For products formulated or applied as gases, any existing glove statement established before the effective date of this subpart, including any glove prohibition statement, will continue to apply. If no glove statement or glove prohibition now exists, the glove

statement shall specify “chemical-resistant (such as nitrile or butyl) gloves.”

(g) *Existing respirator requirement for pesticide handlers on product labeling—*

(1) *General requirement.* If a statement placed on a product's labeling before the effective date of this subpart indicates that respiratory protection is required, that requirement for protection shall be retained. The statement must specify, or be amended to specify, one of the following respirator types and the appropriate MSHA/NIOSH approval number prefix:

(i) Dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C; or

(ii) Respirator with an organic-vapor-removing cartridge and a prefilter approved for pesticides with MSHA/NIOSH approval number prefix TC-23C or with a canister approved for pesticides with MSHA/NIOSH approval number prefix TC-14G; or

(iii) Supplied-air respirator with MSHA/NIOSH approval number prefix TC-19C or self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC-13F.

(2) *Respirator type already specified on labeling.* If the existing respiratory protection requirement specifies a respirator type, it shall be retained. The respirator statement must be revised, if necessary, to conform to the wording in paragraph (g)(1) of this section.

(3) *Respirator type not already specified on labeling.* If the existing respiratory protection requirement on product labeling does not specify a respirator type as listed in paragraph (g)(1) of this section, the specific respirator type shall be that required in the criteria in paragraphs (g)(3)(ii) through (vi) of this section.

(i) *Exception.* The registrant shall specify a different type of respiratory protection device if information, such as vapor pressure value, is available to the registrant to indicate that the type of respiratory protection device selected through the criteria in paragraphs (g)(3)(ii) through (vi) of this section would not be adequately protective, or might increase risks to the user unnecessarily.

(ii) *Gases applied outdoors.* For products that are formulated or applied as

a gas (space and soil fumigants) and that may be used outdoors, the respiratory protection statement shall be: “For handling activities outdoors, use either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).”

(iii) *Gases used in enclosed areas.* For products that are formulated or applied as a gas (space and soil fumigants) and that may be used in greenhouses or other enclosed areas, the respiratory protection statement shall specify: “For handling activities in enclosed areas, use either a supplied-air respirator with MSHA/NIOSH approval number prefix TC-19C, or a self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC-13F.”

(iv) *Solids.* For products that are formulated and applied as solids, the respiratory protection statement shall specify: “dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C).”

(v) *Liquids in toxicity category I.* For products that are formulated or applied as liquids, and, as formulated, have an acute inhalation toxicity (or its surrogate as specified in paragraph (d)(2) of this section) in category I, the respiratory protection statement shall specify: “either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G).”

(vi) *Liquids in toxicity category II.* For products that are formulated or applied as liquids, and, as formulated, have an acute inhalation toxicity (or its surrogate as specified in paragraph (d)(2) of this section) in category II, the respiratory protection statement shall specify: “For handling activities during (select uses applicable to the product: airblast, mistblower, pressure greater than 40 p.s.i. with fine droplets, smoke, mist, fog, aerosol or direct overhead) exposures, wear either a respirator with an organic-vapor-removing cartridge with a prefilter approved

for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G). For all other exposures, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

(h) *New respirator requirement established for pesticide handlers in this part—*

(1) *General requirement.* If the table in paragraph (e) of this section indicates a respiratory protection device is required, and existing product labeling has no respiratory protection requirement, the registrant shall add a respiratory protection statement that specifies a: "dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

(2) *Exception.* The registrant shall specify a different type of respiratory protection device if information, such as vapor pressure value, is available to the registrant to indicate that the type of respiratory protection device required in paragraph (h)(1) of this section would not be adequately protective or might increase risks to the user unnecessarily.

(i) *Additional personal protective equipment requirements for pesticide handlers.* In addition to the minimum personal protective equipment and work clothing requirements given in the table in paragraph (e) of this section, the labeling statement for any product in toxicity category I or II on the basis of dermal toxicity or skin irritation potential (or their surrogate as specified in paragraph (d)(2) of this section), shall include the following personal protective equipment instructions, additions, or substitutions as applicable:

(1) If the product is not ready-to-use and there is no existing requirement for a chemical-resistant suit, the following statement shall be included: "Mixers/Loaders: add a chemical-resistant apron."

(2) If the application of the product may result in overhead exposure to any handler (for example, applicator exposure during airblast spraying of orchards or flagger exposure during aerial application), the following statement shall be included: "Overhead Exposure: wear chemical-resistant headgear."

(3) If any type of equipment other than the product container may be used to mix, load, or apply the product, and there is no requirement for a chemical-resistant protective suit, the following statement shall be included: "For Cleaning Equipment: add a chemical-resistant apron."

(j) *Personal protective equipment for early-entry workers.* This paragraph specifies minimum requirements for personal protective equipment (as defined in §170.240 of this chapter) and work clothing for early-entry workers.

(1) For all pesticide products, add the statement: "For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: (list the body protection, glove, footwear, protective eyewear, and protective headgear, if applicable, statements specified for applicators and other handlers, but omit any respiratory protection statement)."

(2) If the body protection statement in the personal protective equipment requirement for handlers specifies a long-sleeved shirt and long pants, "coveralls" must be specified in the statement of personal protective equipment for early-entry workers.

(3) If there is no statement requiring gloves and no prohibition against gloves for applicators and other handlers under the heading HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) in the labeling, add a requirement for "waterproof gloves" in the statement of personal protective equipment for early-entry workers.

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PART 157—PACKAGING REQUIREMENTS FOR PESTICIDES AND DEVICES

Subpart A [Reserved]

Subpart B—Child-Resistant Packaging

Sec.	
157.20	General.
157.21	Definitions.
157.22	When required.
157.24	Exemptions.